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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,329	04/20/2004	Sonya Montgomery	033136-414	2934
21839	7590	12/23/2005	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/827,329		MONTGOMERY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 30-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/20/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-29, in the reply filed on 3 November 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 30-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 20 April 2004 has been considered. Applicant has provided a list of relevant art and alludes to a PTO-1449, but no such document is found in the case. For clarity, examiner requests that the applicant file a PTO-1449 with relevant art along with the next response.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 3761

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 20-24 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 8 of U.S. Patent No. 6,802,892 to Newman et al in view of US 5,052,382 to Wainwright.

Newman claims the device claimed in the instant invention with the exception of the oxygen and ozone generators.

Wainwright discloses an apparatus for the controlled generation and administration of ozone in order to treat viral and bacterial infections of a patient (see column 1, lines 7-15). Ozone generator 4 and monitor/controller 6 provide a controlled mixture of ozone and oxygen to a fluid sample in flask 82 for administration to a patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an ozone generator as disclosed by Wainwright to the fluid treatment device claimed in patent '382 in order to treat viral and bacterial infections in a patient, as taught by Wainwright.

6. Claims 1, 3, 16, 17, 19, 20-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 10, 11, and 14 of U.S. Patent No. 6,719,715 to Newman et al in view of US 5,052,382 to Wainwright.

Newman claims the device claimed in the instant invention with the exception of the oxygen and ozone generators.

Wainwright discloses an apparatus for the controlled generation and administration of ozone in order to treat viral and bacterial infections of a patient (see column 1, lines 7-15). Ozone generator 4 and monitor/controller 6 provide a controlled mixture of ozone and oxygen to a fluid sample in flask 82 for administration to a patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an ozone generator as disclosed by Wainwright to the fluid treatment device claimed in patent '382 in order to treat viral and bacterial infections in a patient, as taught by Wainwright.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4-15, 18, 19, 25, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,142,971 to Daoud et al. in view of US 5,052,382 to Wainwright.

In the specification and figures, Daoud discloses the apparatus substantially as claimed by applicant. In particular, Daoud discloses a system and method for supersaturating a fluid with a gas, such as oxygen, that may be used to enrich blood to provide systemic support for a patient (see column 1, lines 25-30). The device comprises a cabinet or housing 40 and cylinder or cavity 51 that is hinged along a curved surface (indicating that the hinged area provides a door) to provide access to

Art Unit: 3761

fluid container 70 (see column 3, lines 19-30, column 4, lines 14-22). Inside the housing and cylinder is a removable flask or disposable container 70 (with an internal portion) that comprises an input port 68 connected to the container, a syringe, a tube or cannula, and a two-way valve for input of fluid into the container (see column 4, lines 50-65). The system further comprises a gas source, such as oxygen, that may be coupled to disposable container in combination with the fluid source (see column 5, lines 3-8). After the liquid is saturated with the gas, fluid flows out of the cylinder and container through output tubing 54 into a manifold or receiver 56. Daoud also discloses that his apparatus includes a control interface (generally at 120) that controls operation of the device.

With regard to applicant's limitations drawn to the operation of the controller and components of the device, such limitations are held to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

Daoud fails to disclose an ozone generator along with the oxygen source coupled to the cabinet and flask. However, Daoud does teach that gases other than oxygen may be added to the fluid in disposable container 70 (column 5, lines 3-8). Wainwright discloses an apparatus for the controlled generation and administration of ozone in order to treat viral and bacterial infections of a patient (see column 1, lines 7-15). Ozone generator 4 and monitor/controller 6 provide a controlled mixture of ozone and oxygen to a fluid sample in flask 82 for administration to a patient. Therefore, it would have

been obvious to one having ordinary skill in the art at the time the invention was made to add an ozone generator as disclosed by Wainwright to the fluid treatment device disclosed by Daoud in order to treat viral and bacterial infections in a patient, as taught by Wainwright.

In claim 5, applicant claims that the flask or container has a sufficient volume to permit bubbling of the fluid therein. Since the amount of fluid introduced to the container 70 may vary, at certain volumes, the container will have a sufficient volume to permit bubbling.

In claims 7-15, applicant claims a probe that delivers and withdraws fluid and gas from the flask. Absent any indication to the contrary, examiner interprets the claimed probe to read on the tubing disclosed by Daoud that delivers fluid and gas to and from container 70. Daoud does not disclose that a temperature sensor is located in the lumen of one of the delivery tubes. However, Daoud does disclose thermoresistors 123 located in a recess or socket in the cylinder, protected by film of disposable container 70, that monitor and control the temperature of the fluid in the cylinder and container along with heating jackets (see column 7, lines 53-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the temperature sensor in a delivery lumen or elsewhere in the container (as claimed in claims 9 and 12) rather than in the cylinder wall as disclosed by Daoud, since rearrangement of the working parts of a device involves only routine skill in the art. See MPEP 2144.04.

In claim 19, applicant claims a particular shape to the cabinet. Absent any showing of criticality, it appears to be a matter of obvious design choice to form the cabinet with the claimed recesses and depressions, since applicant has not disclosed that the claimed shape solves any stated problem or is for any particular purpose, and it appears that the invention would perform equally well without the claimed recesses.

9. Claims 3 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,142,971 to Daoud et al. in view of US 5,052,382 to Wainwright as applied above, further in view of US 6,268,119 to Sumita et al.

In the specification and figures, Daoud and Wainwright disclose the device substantially as claimed by applicant with the exception of a heat. Sumita discloses a cell separation apparatus and method that comprises a heat sealer that isolates a desired cell population, delivers the population to a container, and then separates the delivery line from the container via a heat sealer (see column 12, lines 20-32).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a heat sealer as disclosed by Sumita to the modified fluid treatment apparatus disclosed by Daoud in order to sever the delivery line from the fluid container, as taught by Sumita. With regard to applicant's recitation of a second heat sealer, mere duplication of the working parts of a device is within the skill of a worker in the art. See MPEP 2144.04.

10. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,142,971 to Daoud et al. in view of US 5,052,382 to Wainwright as applied above, further in view of US 5,104,373 to Davidner



In the specification and figures, Daoud and Wainwright disclose the device substantially as claimed by applicant with the exception of an infrared or ultraviolet source.

Davidner discloses a blood treatment apparatus that removed blood from a patient, sends it to a treatment loop A, and then exposes the cells to infrared and/or ultraviolet light from sources 172, 174 in order to provide treatment for HIV patients by mechanically damaging infected cells (see column 3, lines 10-20, FIG 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add ultraviolet and infrared light sources, as disclosed by Davidner, to the fluid treatment apparatus disclosed by Daoud, in order to treat HIV-infected patients, as taught by Davidner.

11. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,142,971 to Daoud et al. in view of US 5,052,382 to Wainwright as applied above, further in view of US 5,593,893 to Kobashi et al.

In the specification and figures, Daoud and Wainwright disclose the device substantially as claimed by applicant with the exception of an output syringe pump. Daoud specifically discloses tubing from manifold 56 to fluid delivery device 122, but does not disclose that the fluid delivery device is a syringe.

Kobashi discloses a controller fluid delivery system that uses a syringe 8 and actuator or driving means 18 in order to dispense fluid with high accuracy at great speed (see column 3, lines 30-35, column 8, lines 10-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

substitute an output syringe with actuator, as disclosed by Kobashi, for the output device disclosed by Daoud in order to provide accurate, high-speed fluid dispersion, as taught by Kobashi.

12. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,142,971 to Daoud et al. in view of US 5,052,382 to Wainwright as applied above, further in view of US 5,687,717 to Halpern.

In the specification and figures, Daoud and Wainwright disclose the device substantially as claimed by applicant with the exception of a card reader and printer as a part of the control system. Halpern discloses a patient monitoring system that comprises modules that may be dependent on a treatment device (see column 2, lines 1-15). The modules may comprise a card reader and a printer in order to obtain and transport patient data from the monitor to another machine or paper (column 11, lines 50-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a card reader and a printer, as disclosed by Halpern, to the modified fluid treatment device and controller disclosed by Daoud, in order to transport patient data from one medium to another, as taught by Halpern.

#### ***Allowable Subject Matter***

13. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3761

14. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose or suggest a fluid treatment device with the cabinet, door, input, output, flask, stressors, controller, and output syringe as claimed with the combination of the knocker device of claim 24, along with the other steps and limitations of the claims.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

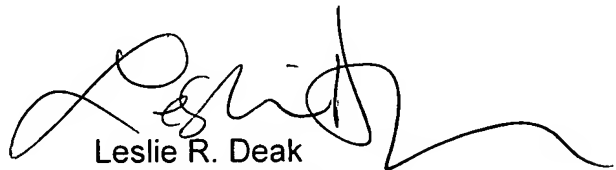
- a. US 5,628,727 Hakky
  - i. Blood treatment device with ultraviolet source
- b. US 6,613,280 Myrick et al
  - ii. Blood treatment device with cabinet, door, and ozone delivery

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Leslie R. Deak', is positioned above the printed name and title.

Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
14 December 2005